



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2011-0308; FRL-8869-3]

Extension of Review Periods Under the Toxic Substances Control Act; Certain Chemicals and Microorganisms; Premanufacture, Significant New Use, and Exemption Notices; Delay in Processing Due to Lack of Authorized Funding

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Due to the federal government shutdown related to the lack of authorized funding (i.e., a Fiscal Year 2014 Appropriations Bill or a Continuing Resolution), EPA is extending the review periods for all Premanufacture Notices (PMNs), Significant New Use Notices (SNUNs), Microbial Commercial Activity Notices (MCANs), and exemption notices submitted to the Agency under section 5 of the Toxic Substances Control Act (TSCA), received by EPA on or before October 1, 2013, and for which the review period had not expired as of October 1, 2013. Additionally, EPA did not receive notifications with respect to such submissions on or after October 1, 2013, and before the date on which the shutdown terminated on October 16, 2013, and the affected operations resumed on October 17, 2013. Also, during the shutdown, submissions made through e-PMN/CDX or other methods were not processed by EPA. Consequently, the review period for any TSCA section 5 notice submitted during the shutdown did not begin until operations resumed on October 17, 2013.

DATES: The duration of this extension period is equivalent to the duration of the shutdown, i.e., 16 days (equivalent to the number of days accruing from October 1, 2013 to October 16, 2013).

FOR FURTHER INFORMATION CONTACT: Greg Schweer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8469; e-mail address: *schweer.greg@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Document Apply to Me?

You may be affected by this document if you are, or may in the future be, a manufacturer, importer, or processor of a chemical substance that requires submission of a PMN, MCAN, SNUN, or exemption notice under section 5 of TSCA (15 U.S.C. 2604) and applicable EPA regulations. Potentially affected entities may include:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

The North American Industrial Classification System (NAICS) codes listed are not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information?

Information about the TSCA section 5 requirements can be found at

<http://www.epa.gov/oppt/newchems/>.

C. What is the Agency's Authority for Taking this Action?

Under TSCA section 5(c), 15 U.S.C. 2604(c), EPA has authority for good cause to unilaterally extend the notice review period for PMNs, MCANs, and SNUNs, thereby extending the period before manufacturing or processing the subject chemical substances may begin. (See also 40 CFR 720.75(c) for PMNs and SNUNs, and 40 CFR 725.56 for MCANs.) TSCA section 26(c), 15 U.S.C. 2625(c), authorizes EPA to take action with respect to a category of chemical substances; in this case, the category is all chemical substances that are the subject of the specified notices and exemption applications received before October 1, 2013, for which the notice review period would otherwise expire on or after October 1, 2013. Under TSCA section 5(c), extensions of the review period for an individual TSCA section 5 notice shall not total more than 90 days. Because the extension described in this **Federal Register** notice (i.e., 16 days) is less than 90 days, EPA reserves the right under TSCA section 5(c) to issue, for good cause, future additional extensions for individual cases up to a total of 90 days.

TSCA section 5(h), 15 U.S.C. 2604(h), authorizes EPA to exempt manufacturers and/or processors of chemical substances from all or part of the requirements of section 5 if EPA determines that the proposed manufacture, processing, distribution in commerce, use, or disposal of such chemical substance will not present an unreasonable risk to health or the environment. Pursuant to this and other authorities, EPA has concluded that the additional time specified in this notice is required to evaluate the exemption applications described in Unit II.A., and determine whether the chemical substances that are the subject of these exemption applications will not present an unreasonable risk.

II. Extension of Review Periods

A. Which TSCA Review Periods are Affected?

Section 5 of TSCA and 40 CFR part 720 require any person who intends to manufacture (defined by statute to include import) a new chemical substance (i.e., a chemical not on the TSCA section 8(b) Inventory) to notify EPA at least 90 days before commencing non-exempt commercial manufacture in the form of a PMN. At least 90 days advance notice for manufacture of new microorganisms is required under 40 CFR part 725, in the form of an MCAN. Under section 5 of TSCA and 40 CFR part 721, any person intending to manufacture or process a chemical substance for a significant new use, as designated by EPA in a SNUR, must also give EPA at least 90 days advance notice in the form of a SNUN. SNURs for microorganisms appear at 40 CFR part 725, subpart M.

There are a number of exemptions from the above-described 90-day PMN, MCAN, and SNUN notice requirements. Several of these exemptions require submitting to EPA a written notice or application, which is subject to a review period shorter than 90 days. For example, pursuant to TSCA section 5(h)(1), EPA has promulgated a Test Market Exemption (TME) from the PMN, MCAN, and SNUN 90-day notice requirements. The TME from the PMN requirement appears at 40 CFR 720.38; the TME from the MCAN requirement is codified in 40 CFR part 725, subpart F (40 CFR 725.300 through 725.370); and the TME from the SNUN requirement appears at 40 CFR 721.45(a). Under TSCA section 5(h)(4), EPA promulgated at 40 CFR 723.50 a Low Volume Exemption (LVE) and a Low Release/Low Exposure (LOREX) Exemption from the PMN requirement. The regulations at 40 CFR part 725 pertaining to genetically

engineered microorganisms provide several exemptions from the 90-day MCAN requirement, including the TSCA Experimental Release Application (TERA) at 40 CFR part 725, subpart E, and the Tier I and Tier II Exemptions at 40 CFR part 725, subpart G.

B. What Action is the Agency Taking?

Effective October 1, 2013, due to the lack of authorized funding (i.e., a Fiscal Year 2014 Appropriations Bill or a Continuing Resolution), certain EPA functions were suspended. During the shutdown, no review work was performed on the TSCA section 5 notifications received by EPA on or before October 1, 2013, and for which the review period had not yet expired as of October 1, 2013. Because of the shutdown, EPA is now extending, pursuant to TSCA sections 5(c) and 26(c) and 40 CFR 720.75(c), the review periods of all TSCA section 5 notifications received on or before October 1, 2013, and for which the review period has not yet expired as of October 1, 2013.

There is a possibility that the chemical substances submitted for review in these TSCA section 5 notifications may need to be regulated by EPA under TSCA. The Agency requires an extension of the review periods to complete its risk assessment, to examine its regulatory options, and to prepare the necessary documents, should regulatory action be required. Therefore, EPA has determined that good cause exists to extend, under TSCA section 5(c), the review period for each such TSCA section 5 notification.

The duration of this extension period is equivalent to the duration of the shutdown, i.e., equivalent to the number of days accruing from October 1, 2013, and the date on which this shutdown terminated on October 16, 2013, and EPA operations resumed on October 17, 2013, or a total of 16 days. Under TSCA section 5(c), the total

extensions of the review period for an individual PMN shall in no event exceed 90 days. Thus, since the extension described in this notice is for less than 90 days, EPA reserves the right to issue additional extensions under TSCA section 5(c) in the future for good cause up to a total of 90 days.

Because of these circumstances, EPA is taking the following actions and is requesting the assistance of notifiers as described in this unit:

Category 1--TSCA section 5 notices and exemptions submitted to EPA on or after October 1, 2013, and before the date on which the affected operations resumed on October 17, 2013. During the shutdown, submissions made through e-PMN/CDX or other methods were not processed. Consequently, the review period for any TSCA section 5 notice submitted during the shutdown did not begin until operations resumed on October 17, 2013.

Category 2--TSCA section 5 exemption notices scheduled to expire on or after October 1, 2013. For any exemption notices that have not been granted by EPA and for which the review period was scheduled to expire on or after October 1, 2013, EPA is hereby extending the notice review period by 16 days (the number of days equivalent to the duration of the shutdown). This additional time is required to ensure there is sufficient opportunity to determine that the chemical substances that are the subject of the exemption applications will not present an unreasonable risk.

Category 3--TSCA section 5 PMNs, MCANs, and SNUNs scheduled to expire on or after October 1, 2013. For any PMN, MCAN, or SNUN for which the review period was scheduled to expire on or after October 1, 2013, EPA is hereby extending the

notice review period by 16 days (the number of days equivalent to the duration of the shutdown).

C. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before the Agency can impose binding requirements like those contained in a rule, the Agency must submit a rule report, which includes a copy of the document, to each House of the Congress and to the Comptroller General of the United States. Although this document is not a rule, it is binding in the sense that the suspension of the review periods announced in this document are binding. EPA has submitted a report to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this document in the **Federal Register**.

List of Subjects

Environmental protection, Chemicals, Microbial Commercial Activity Notices, Microorganisms, Premanufacture Notices, Significant New Use Notices, Test Marketing Exemptions.

Dated: October 21, 2013.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

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